Template Instructions

What do the colors mean?

- Green text indicates an instruction to the IC. Please remove all instructions before submission.
- Text with a yellow background indicates that the IC may edit an item. ICs should not remove the yellow background before submission.
- Any other text either must be included or should be included as appropriate. The instructions should make it clear under what conditions the IC must select additional boilerplate.

Dos and Don'ts

- When pasting text into the document, you will want to paste plain text by choosing: "edit / paste special / unformatted text" which will preserve the font choices and highlighting that is appropriate for that field.
- Do not underline.
- Do not add additional indentation.
- Do not leave the track changes feature of MS Word on.
- Do make sure that all URLs are complete and operational.
- Do not remove any of the headings or sub-headings.
- Do indicate if a particular heading or sub-heading is Not Applicable.

Additional Guidance may be found at http://odoerdb2.od.nih.gov/oer/policies/pol_guide_inst.htm

Template Date: This template was last modified on April 6, 2005

Template Type: PA. It can be used for any Non-SBIR/STTR PA, PAS or PAR.

Part I Overview Information

Department of Health and Human Services

Issuing Organization
(Required, but will not appear in published Guide document)
(e.g., National Institutes on Drug Abuse (NIDA) (http://www.nida.nih.gov))

Participating Organizations
Required. Spell out the name of the participating organization using upper and lowercase, one organization per line, include organization abbreviations, include URL to organization homepage. [e.g. National Institutes of Health (NIH) (http://www.nih.gov)]
Add Information Here

Components of Participating Organizations
Required. Spell out the name of the component using upper and lower case, one component per line, include component abbreviation, include url to component homepage. [e.g. National Institute on Aging (NIA/NIH) (http://www.nia.nih.gov)]
Add Information Here

Title: Add Title Here

Note: The policies, guidelines, terms, and conditions stated in this announcement may differ from those used by the NIH.

Include above statement only if NIH is not involved. If NIH is involved, even as a collaborator, then NIH policies must be followed and this statement is not necessary.

Announcement Type
Required. Indicate whether this is an initial/new announcement by simply typing New, or a modification/amendment of a prior announcement. If it is a modification or a reissue of a funding opportunity, provide number and date of prior announcement (e.g., "This is a reissue of PA-xx-xxx" or "This is a modification of RFA-xx-xx-xxx which was previously released May 15, 1998").
Add Information Here

Program Announcement (PA) Number: PA-(Number Here)

TPA Number:
(Required, but will not appear in published Guide document)

Catalog of Federal Domestic Assistance Number(s)
Required. List all appropriate CFDA numbers for this program. See available CFDA numbers at http://oerdb.od.nih.gov/cfdocs/ens/CFDANumbers.htm.
Add Information Here

Key Dates
For Application Receipt, Peer Review and Council Review dates, the IC should either state

"Standard dates apply, please see http://grants1.nih.gov/grants/funding/submissionschedule.htm for details" OR if non-standard dates are used, list the actual dates.

Release Date: Leave blank
Letters of Intent Receipt Date(s): Add Information Here optional, for PARs only. Note that the Letter of Intent cannot be more than 30 days before receipt date.
Application Receipt or Submission Dates(s): Add Information Here Label this item as Application Receipt Dates only if special dates have been negotiated with the Division of Receipt and Referral, otherwise this item should be labeled Application Submission Dates. For PARs this date(s) must be at least 60 days after publication of the announcement, and must be negotiated with the Division of Receipt and Referral.
AIDS Application Receipt Dates(s): Add Information Here Optional. Provide receipt dates for AIDS applicants if appropriate. See http://grants1.nih.gov/grants/funding/submissionschedule.htm#AIDS for guidance on dates.
Peer Review Date(s): Add Information Here Required, see http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward for guidance on dates.
Council Review Date(s): Add Information Here Required , see http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward for guidance on dates.
Earliest Anticipated Start Date: Add Information Here Required , see http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward for guidance on dates.
Additional Information To Be Available Date (Url Activation Date): Add Information Here
Expiration Date:_____ required, insert complete date in the format mm/dd/yyyy. Note that PAs normally have a life span of three years (nine receipt cycles) from the first application receipt/submission date after which the PA must be re-issued or terminated. The expiration date must be the day after the last application receipt/submission date. Please see (http://grants1.nih.gov/grants/funding/submissionschedule.htm) to determine your final application receipt/submission date and add a day to calculate your expiration date. Remember to consider revision dates and AIDS dates when making this calculation.

Due Dates for E.O. 12372

(Single Point of Contact programs are only rarely applicable for NIH. See http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part9.htm#_Toc54600164 for details.)

Not Applicable

Additional Overview Content

Executive Summary

Include an executive summary of the announcement before the full text making sure that the information presented here is consistent with information presented in the full text. Information **must** be presented in bulleted format. Please keep in mind that readers will appreciate clarity and brevity.

- A concise description of the funding opportunity.
- The total amount to be awarded and the anticipated number of awards. (If this information is uncertain, you may use the next bulleted item instead.)
- Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. The total amount awarded and the number of awards will depend upon the mechanism numbers, quality, duration, and costs of the applications received.

- The types of mechanisms.
- Eligible organizations include.
- Eligible principal investigators include...
- Applicants may submit more than one application, provided they are scientifically distinct. (NIH announcements should include the above sentence unless there are specific deviations from this rule)
- See Section IV.1 for application materials.
- Telecommunications for the hearing impaired is available at: TTY 301-451-0088

Table of Contents

Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

The **PURPOSE** of the funding opportunity may be presented in paragraph form as long as all of the bulleted items are addressed. Please keep in mind that readers will appreciate clarity and brevity.

- Nature of the research opportunity
- Pertinent background information that establishes the need for the research
- Scientific knowledge to be achieved through research supported by the special program
- Objectives of this research program
- Identify the types of research and experimental approaches that are being sought to achieve the objectives
- Examples of research topics may be presented if appropriate

See Section VIII, Other Information - Required Federal Citations, for policies related to this announcement.

Add Additional Information Here

Section II. Award Information

1. Mechanism(s) of Support

This section must indicate the type(s) of assistance instrument (e.g., grant or cooperative agreement) that may be awarded if applications are successful. If appropriate, include the paragraph for cooperative agreements. Note that modular budgets are limited to the following mechanisms: R01, R03, R15, and R21. (See also Section IV.6. Other Submission Requirements.)

(Paragraph 1.)

Fill in blank with the appropriate mechanism(s). Note that R01s have no dollar limit, but other mechanisms may include limits in the requested amount and duration as appropriate.
This funding opportunity will use the Add Information Here award mechanism(s).

As an applicant, you will be solely responsible for planning, directing, and executing the proposed project.

(Paragraph 2 for modular and non-modular budget format - use only if mechanisms are limited to R01, R03, R15, and R21)
This funding opportunity uses just-in-time concepts. It also uses the modular as well as the non-modular budget formats (see http://grants.nih.gov/grants/funding/modular/modular.htm). Specifically, if you are submitting an application with direct costs in each year of $250,000 or less, use the modular budget format described in the PHS 398 application instructions. Otherwise follow the instructions for non-modular research grant applications.

(or)

(Paragraph 3 for modular budget format - use only if mechanisms are limited to R01, R03, R15 and R21)
This funding opportunity uses just-in-time concepts. It also uses the modular budget format described in the PHS 398 application instructions (see http://grants.nih.gov/grants/funding/modular/modular.htm).

(or)

(Paragraph 4 for non-modular budget format)
This funding opportunity uses the just-in-time budget concepts. It also uses the non-modular budget format described in the PHS 398 application instructions (see http://grants.nih.gov/grants/funding/phs398/phs398.html). A detailed categorical budget for the "Initial Budget Period" and the "Entire Proposed Period of Support" is to be submitted with the application.

(Paragraph 5 for cooperative agreements only)
(Indicate activity code in the blank provided if applicable)
The NIH (Insert Activity Code Here) is a cooperative agreement award mechanism. In the cooperative agreement mechanism, the Principal Investigator retains the primary responsibility and dominant role for planning, directing, and executing the proposed project, with NIH staff being substantially involved as a partner with the Principal Investigator, as described under the Section VI. 2. Administrative Requirements, "Cooperative Agreement Terms and Conditions of Award". (Also indicate current organization's program intentions, e.g.: to continue the cooperative agreement project(s) beyond the initially awarded period of performance; or to reissue the funding opportunity or other announcement; or to convert these awards to grants or contracts after the initial award period; or if plans beyond the current funding opportunity are indefinite.)

2. Funds Available

Required. Information may be presented in paragraph as long as all of the bulleted items are addressed.

- total amount of funding that your agency/IC expects to award through this announcement;
- the anticipated number of awards;
- the expected amount for individual awards [which may be a range]; (Direct Costs only, cannot be total costs. Note that this applies to NIH Institutes and Centers only.)
- the amount of funding per award, on average, experienced in previous years; and (If Appropriate)
- the anticipated start dates and periods of performance for new awards.

The following paragraph may be removed if it is not applicable. Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the IC(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

Facilities and administrative costs requested by consortium participants are not included in the direct cost limitation, see NOT-OD-05-004.

Section III. Eligibility Information

This section addresses considerations or factors that make an applicant or application eligible or ineligible for consideration. Organizations/ICs should make it clear whether applicants' failure to meet an eligibility criterion by the time of an application deadline will result in the return of the application without review, or even though the application may be reviewed, will preclude the agency from making an award. Address whether applications for renewal or supplementation of existing projects are eligible to compete with applications for new awards.

1. Eligible Applicants

1.A. Eligible Institutions

(You must select all categories that apply. Bulleted items may be included or excluded but not changed.)

You may submit (an) application(s) if your organization has any of the following characteristics:

- For-profit organizations
- Non-profit organizations
- Public or private institutions, such as universities, colleges, hospitals, and laboratories
- Units of State government
- Units of local government
- Eligible agencies of the Federal government
- Foreign Institutions
- Domestic Institutions
- Faith-based or community-based organizations

Add Additional Information Here if Appropriate

For Foreign Institutions: Organizations/ICs should include when awards are restricted by policy or regulations to domestic institutions/organizations. If collaborators at foreign institutions are allowed, describe conditions for collaboration.

For faith-based organizations: OEP may request inclusion of this category in specific funding opportunities. Organizations/ICs must clearly identify the types of entities that are eligible to apply. If there are restrictions on eligibility, be clear about types that are ineligible, e.g., if Native American tribal organizations are eligible, state that rather than assume that they are included under the statement that non-profit organizations may apply.

1.B. Eligible Individuals

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs. (Note: some NIH programs, like NIH training and career development programs, may limit eligibility to individuals with specified degrees, prior training, or citizenship status. Include special eligibility criteria in this paragraph.)
Add Information Here

2. Cost Sharing or Matching

State whether there is a required cost sharing, matching, or cost participation without which an application would be ineligible; also state if cost sharing is not required. Cost sharing as an eligibility criterion includes requirements based in statute or regulation, as well as those imposed by administrative decision of the agency.

Add Information Here

The most current Grants Policy Statement can be found at:
http://grants.nih.gov/grants/policy/nihgps_2003/nihgps_Part2.htm#matching_or_cost_sharing

3. Other-Special Eligibility Criteria

Required. This section contains other eligibility criteria if applicable (e.g., responsiveness criteria, threshold criteria, if entities have violated a particular statute). Also state if there is any limit to the number of applications an applicant may submit under the announcement.
Add Information Here

Section IV. Application and Submission Information

1. Address to Request Application Information

The PHS 398 application instructions are available at http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format. Applicants must use the currently approved version of the PHS 398. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

Telecommunications for the hearing impaired: TTY 301-451-0088.

2. Content and Form of Application Submission

Applications must be prepared using the most current PHS 398 research grant application instructions and forms. Applications must have a D&B Data Universal Numbering System (DUNS) number as the universal identifier when applying for Federal grants or cooperative agreements. The D&B number can be obtained by calling (866) 705-5711 or through the web site at http://www.dnb.com/us/. The D&B number should be entered on line 11 of the face page of the PHS 398 form.

The title and number of this funding opportunity must be typed on line 2 of the face page of the application form and the YES box must be checked.

Add Information Here

If foreign organizations are allowed, include the text below.

Foreign Organizations

Several special provisions apply to applications submitted by foreign organizations:

- Charge back of customs and import fees is not allowed.
- Format: every effort should be made to comply with the format specifications (http://www.format.nih.gov/FAQ/FAQ.htm), which are based upon a standard US paper size of 8.5" x 11."
- Funds for up to 8% administrative costs (excluding equipment) can now be requested (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-028.html)
- Organizations must comply with federal/NIH policies on human subjects, animals, and biohazards.
- Organizations must comply with federal/NIH biosafety and biosecurity regulations. See Section VI. 2. Administrative Requirements http://oerdbdev.od.nih.gov/AGS/Admin/BoilerPlate/ShowDraftRFA.cfm , "Cooperative Agreement Terms and Conditions of Award".

Proposed research should provide a unique research opportunity not available in the U.S.

3. Submission Dates and Times

See section Section IV.3.C for details.

3.A. Receipt, Review and Anticipated Start Dates

Choose this header if special dates have been negotiated with the Division of Receipt and Referral. When choosing this header, be sure to delete 3.A. below. Also, be sure that the dates here match the dates on the face page.

Letter of Intent **Receipt** Date:
Application Receipt Date(s):
Peer Review Date:
Council Review Date:
Earliest Anticipated Start Date:

3.A. Submission, Review and Anticipated Start Dates

Choose this header if standard dates are to be used. When choosing this header, be sure to delete 3.A. above.

Letter of Intent **Submission** Date:
Application Submission Date(s):
Peer Review Date:
Council Review Date:
Earliest Anticipated Start Date:

3.A.1. Letter of Intent

(Select text block 1 or 2)
(Agencies other than NIH may alter the text block below. If NIH is involved, text block 1 may not be altered.)

(**Text block 1**, use for PARs only. Note that only the information listed in the bulleted items below may be requested.)
Prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed research

- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Number and title of this funding opportunity

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed at the beginning of this document.

The letter of intent should be sent to:

Use minimum information necessary in all addresses.
FAX Number is optional, Email address is required.

Staff Contact Name
Division
Institute or Center
Street Address
Building Number, Room Number
Bethesda, MD 20892
Telephone: (301) NNN-NNNN
FAX:
Email:

(**Text block 2**, use for PA or PAS only)
A letter of intent is not required for the funding opportunity.

3.B. Sending an Application to the NIH

Note: For PARs, when IC reviews applications, 2 copies of the application go to the IC; CSR receives the original plus 3 copies. Total number of applications to CSR plus the IC cannot exceed 6.

Applications must be prepared using the research grant application forms found in the PHS 398 instructions for preparing a research grant application. Submit a signed, typewritten original of the application, including the checklist, and five signed photocopies in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710 (U.S. Postal Service Express or regular mail)
Bethesda, MD 20817 (for express/courier service; non-USPS service)

Personal deliveries of applications are no longer permitted (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-040.html).

3.C. Application Processing

For PARs with special receipt dates approved by DRR, select paragraph 2. For all others, select Paragraph 1.

(Paragraph 1)
Applications must be **submitted on or before the application receipt/submission dates** described above (Section IV.3.A.) and at http://grants.nih.gov/grants/dates.htm.

(Paragraph 2)
Applications must be **received on or before the application receipt/submission date(s)** described above (Section IV.3.A.). If an application is received after that date, it will be returned to the applicant without review .

(Paragraph 3 required)
Upon receipt applications will be evaluated for completeness by CSR. Incomplete applications will not be reviewed.

(Paragraph 4 required)
The NIH will not accept any application in response to this funding opportunity that is essentially the same as one currently pending initial merit review unless the applicant withdraws the pending application. The NIH will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of a substantial revision of an application already reviewed, but such application must include an Introduction addressing the previous critique.

(Paragraph 5 required)
Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within eight (8) weeks.

4. Intergovernmental Review

(NIH will ordinarily use the text below.)
This initiative is not subject to intergovernmental review.

5. Funding Restrictions

(NIH and other agencies should add instructions that govern the use of funds available through these awards.)

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The Grants Policy Statement can be found at http://grants.nih.gov/grants/policy/policy.htm.
Add Information Here

(Non NIH agencies should delete the following paragraph. NIH ICs may add additional information as appropriate)

Pre-Award Costs are allowable. A grantee may, at its own risk and without NIH prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new or competing continuation award if such costs: are necessary to conduct the project, and would be allowable under the grant, if awarded, without NIH prior approval. If specific expenditures would otherwise require prior approval, the grantee must obtain NIH approval before incurring the cost. NIH prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new or competing continuation award.

The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on NIH either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. NIH expects the grantee to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the grantee's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project. See NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part6.htm.

Add Additional Information Here

6. Other Submission Requirements

Include any supplementary instructions not stated elsewhere in the announcement. Identify any special requirements or performance requirements that should be stated when the application is submitted. For example, for clinical research, the ability to enroll a specified number of patients; special expertise or facilities required; requirements for coordination among investigators [e.g. annual meetings] Applicants should be advised to include the cost for such items in the budget. For cooperative agreements, awardees must agree to the "Cooperative Agreement Terms and Conditions of Award" in Section VI. "Award Administration Information". Note that special guidelines must be cleared in advance by OEP.

Specific Instructions for Modular Grant applications. (Include if appropriate - and funding opportunity is using one or more of the following mechanisms - R01, R03, R15, R21. Do not include for cooperative agreements.)

Applications requesting up to $250,000 per year in direct costs must be submitted in a modular budget format. The modular budget format simplifies the preparation of the budget in these applications by limiting the level of budgetary detail. Applicants request direct costs in $25,000 modules. Section C of the research grant application instructions for the PHS 398 at http://grants.nih.gov/grants/funding/phs398/phs398.html includes step-by-step guidance for preparing modular budgets. Applicants must use the currently approved version of the PHS 398. Additional information on modular budgets is available at http://grants.nih.gov/grants/funding/modular/modular.htm. (See also Section II.1. Mechanisms of Support)

Specific Instructions for Applications Requesting $500,000 (direct costs) or More per Year. Include if appropriate. (See also Section VIII-Other Information)

Applicants requesting $500,000 or more in direct costs for any year must carry out the following steps:

1) Contact the IC program staff at least 6 weeks before submitting the application, i.e., as you are developing plans for the study;

2) Obtain agreement from the IC staff that the IC will accept your application for consideration for award; and,

3) Include a cover letter with the application that identifies the staff member and IC who agreed to accept assignment of the application.

This policy applies to all investigator-initiated new (type 1), competing continuation (type 2), competing supplement, or any amended or revised version of these grant application types. Additional information on this policy is available in the NIH Guide for Grants and Contracts, October 19, 2001 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html.

Plan for Sharing Research Data

Choose this paragraph if it accurately describes the IC's approach to the data sharing plan. If not, the IC should substitute their own guidance here.

The precise content of the data-sharing plan will vary, depending on the data being collected and how the investigator is planning to share the data. Applicants who are planning to share data may wish to describe briefly the expected schedule for data sharing, the format of the final dataset, the documentation to be provided, whether or not any analytic tools also will be provided, whether or not a data-sharing agreement will be required and, if so, a brief description of such an agreement (including the criteria for deciding who can receive the data and whether or not any conditions will be placed on their use), and the mode of data sharing (e.g., under their own auspices by mailing a disk or posting data on their institutional or personal website, through a data archive or enclave). Investigators choosing to share under their own auspices may wish to enter into a data-sharing agreement. References to data sharing may also be appropriate in other sections of the application.

If a data sharing plan will only be required for applications requesting $500,000 or more in direct costs the IC should include instruction 1. If a data sharing plan will be required regardless of the dollar amount requested, the IC should include instruction 2. Note that only one set of instructions should be included.

(Instruction 1)
Applicants requesting more than $500,000 in direct costs in any year of the proposed research must include a plan for sharing research data in their application. The funding organization will be responsible for monitoring the data sharing policy (http://grants.nih.gov/grants/policy/data_sharing).

The reasonableness of the data sharing plan or the rationale for not sharing research data may be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score.

(or)

(Instruction 2)
Describe any requirements for sharing of research data, regardless of the direct costs requested, in any year of the proposed research. Review considerations should be addressed in Section V.
All applicants must include a plan for sharing research data in their application. The data sharing policy is available at http://grants.nih.gov/grants/policy/data_sharing. All investigators responding to this funding opportunity should include a description of how final research data will be shared, or explain why data sharing is not possible.

The reasonableness of the data sharing plan or the rationale for not sharing research data will be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score.
Add Information Here

Sharing Research Resources

(Include this paragraph if there is a potential for developing research resources.)

NIH policy requires that grant awardee recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication (NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/index.htm and http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm#_Toc54600131). Investigators responding to this funding opportunity should include a plan for sharing research resources addressing how unique research resources will be shared or explain why sharing is not possible.

The adequacy of the resources sharing plan and any related data sharing plans will be considered by Program staff of the funding organization when making recommendations about funding applications. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report (PHS 2590, http://grants.nih.gov/grants/funding/2590/2590.htm). See Section VI.3. Reporting.

The funding organization should provide additional instructions as appropriate here.
Add Information Here

Section V. Application Review Information

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1. Criteria

In addition to the criteria cited below, this section includes any statutory or regulatory or other preferences that will be applied in the review process (e.g., minority or Native American tribal preferences). If the announcement requires cost sharing, either state that it will not be considered or state how it will be considered. See also Section III. Eligibility Information 1. A., and B.

Select the following sentence if appropriate:
Only the review criteria described below will be considered in the review process.

Add Information Here

2. Review and Selection Process

This section may vary in level of detail but must list any program policy or other factors or elements other than merit criteria, that the selecting official may use in selecting applications for award, e.g., geographical, program balance, diversity etc., multi-phase review process. Non-NIH agencies should insert information appropriate for their process.

Applications submitted for this funding opportunity will be assigned to the ICs on the basis of established PHS referral guidelines.

Appropriate scientific review groups convened in accordance with the standard NIH peer review procedures (http://www.csr.nih.gov/refrev.htm) will evaluate applications for scientific and technical merit.

If a PAR with IC review, use the following language:
Applications that are complete will be evaluated for scientific and technical merit by an appropriate review group convened by (Add IC Here) in accordance with the review criteria stated below.

As part of the initial merit review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score.
- Receive a written critique
- Receive a second level of review by an appropriate national advisory council or board. (For second level of review, if PAR and applications will be considered by a single IC, insert IC Name.)

The following will be considered in making funding decisions:

- Scientific merit of the proposed project as determined by peer review
- Availability of funds
- Relevance of program priorities

In addition to the above, indicate if this award would include special terms and conditions that differ from the agency's usual terms and conditions. Include Programmatic Priorities and Other Cost Limitations (e.g., excluding Facilities & Administrative costs for R13s). See also section IV.5 Funding Restrictions.
Add Information Here

(Note that the review criteria should not be modified for standard PAs)

The goals of NIH supported research are to advance our understanding of biological systems, to improve the control of disease, and to enhance health. In their written critiques, reviewers will be asked to comment on each of the following criteria in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that an application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? Information May be Added Here

Approach: Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Information May be Added Here

Innovation: Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area? Information May be Added Here

Investigators: Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)? Information May be Added Here

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support? Information May be Added Here

2.A. Additional Review Criteria:

Select all that apply

In addition to the above criteria, the following items will continue to be considered in the determination of scientific merit and the priority score:

Protection of Human Subjects from Research Risk: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed (see the Research Plan, Section E on Human Subjects in the PHS Form 398).

Inclusion of Women, Minorities and Children in Research: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated (see the Research Plan, Section E on Human Subjects in the PHS Form 398).

Care and Use of Vertebrate Animals in Research: If vertebrate animals are to be used in the project, the five items described under Section F of the PHS Form 398 research grant application instructions will be assessed.

Biohazards: If materials or procedures are proposed that are potentially hazardous to research personnel and/or the environment, determine if the proposed protection is adequate.

2.B. Additional Review Considerations

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research. The priority score should not be affected by the evaluation of the budget.

2.C. Sharing Research Data

If a data sharing plan will only be required for applications requesting $500,000 or more in direct costs select instruction 1. If a data sharing plan will be required regardless of the dollar amount, include instruction 2.

1. **Data Sharing Plan:** The reasonableness of the data sharing plan or the rationale for not sharing research data may be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score. The funding organization will be responsible for monitoring the data sharing policy. http://grants.nih.gov/grants/policy/data_sharing. Information May be Added Here

(If reviewers will be asked to assess the adequacy of the plan, include additional guidance in this Section. If not, indicate that program staff will be responsible for the administrative review of the plan for sharing research data.)

2. **Data Sharing Plan:** The reasonableness of the data sharing plan or the rationale for not sharing research data will be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score. The presence of a data sharing plan will be part of the terms and conditions of the award. The funding organization will be responsible for monitoring the data sharing policy. Information May be Added Here

2.D. Sharing Research Resources

Include this paragraph if there is a potential for developing research resources.

NIH policy requires that grant awardee recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication (See the NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps/part_ii_5.htm#availofrr and http://ott.od.nih.gov/RTguide_final.html). Investigators responding to this funding opportunity should include a sharing research resources plan addressing how unique research resources will be shared or explain why sharing is not possible.

(If reviewers will be asked to assess the adequacy of the plan, include guidance in this Section. If not choose the following sentence.)

Program staff will be responsible for the administrative review of the plan for sharing research resources.

The adequacy of the resources sharing plan will be considered by Program staff of the funding organization when making recommendations about funding applications. Program staff may negotiate modifications of the data and resource sharing plans with the awardee before recommending funding of an application. The final version of the data and resource sharing plans negotiated by both will become a condition of the award of the grant. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report (PHS 2590). See Section VI.3. Reporting.

3. Anticipated Announcement and Award Dates

This section should be used if the intent is to include information about when applicants can expect to learn about the outcome of their applications, whether successful of unsuccessful. Add N/A if not applicable.

Section VI. Award Administration Information

1. Award Notices

After the peer review of the application is completed, the Principal Investigator will also receive a written critique called a Summary Statement.

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant. For details, applicants may refer to the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_part4.htm).

A formal notification in the form of a Notice of Grant Award (NGA) will be provided to the applicant organization. The NGA signed by the grants management officer is the authorizing document. Once all administrative and programmatic issues have been resolved, the Notice of Grant Award will be generated via email notification from the awarding component to the grantee business official (designated in item 14 on the Application Face Page). If a grantee is not email enabled, a hard copy of the Notice of Grant Award will be mailed to the business official.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NGA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs. See Also Section IV.5. Funding Restrictions.
Add any additional information here

2. Administrative and National Policy Requirements

Identify terms and conditions/requirements that the awards include, so that potential applicants may identify any with which compliance would be difficult (e.g., if human subjects are involved or if there are special terms on intellectual property, data sharing, or security requirements). See also VIII-Other Information for required Federal Citations and provide additional instruction here, as appropriate; and subsection IV.5. Funding Restrictions.
Add Information Here

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement as part of the notice of grant award. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part4.htm) and Part II Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_part9.htm).

The following Terms and Conditions will be incorporated into the award statement and will be provided to the Principal Investigator as well as to the appropriate institutional official, at the time of award.

Add Sections 2.A. and 2.A.1 through 2.A.4, only if the announcement contains a cooperative agreement mechanism. For cooperative agreements, a section titled "Cooperative Agreement Terms and Conditions of Award" will be included here in the funding opportunity. The following standard language and format are required. NIH staff may also refer to the NIH Guide for recent examples (within the past two years) of cooperative agreement Terms and Conditions.

2.A. Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines, HHS grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is

applicable when State and local Governments are eligible to apply), and other HHS, PHS, and NIH grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement (Add Information Here U Add Information Here), an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the NIH as defined above.

2.A.1. Principal Investigator Rights and Responsibilities
The Principal Investigator will have the primary responsibility for: (provide specific language)
Add Information Here

Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current HHS, PHS, and NIH policies.

2.A.2. NIH Responsibilities
(if an NIH project scientist is not involved, provide other functional title where appropriate below)
An NIH Project Scientist will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below. (Provide specific language)
Add Information Here

Additionally, an agency program official or IC program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice. (if the same individual will serve as both the program director as well as the "NIH Project Scientist": The assigned program director may also serve as an NIH Project Scientist.)

2.A.3. Collaborative Responsibilities (optional)
In this section, the IC should describe any areas of joint responsibility, including membership, duties, voting, etc. For example: A steering committee will serve as the governing board for the award or group of awards. Membership will include: (define PI(s), etc.; NIH representation should be limited to NIH Project Scientist if possible, and should not be the Chair.)
Add Information Here

Each full member will have one vote. Awardee members of the Steering Committee will be required to accept and implement policies approved by the Steering Committee.

2.A.4. Arbitration Process

(Non-NIH Agencies may delete if not applicable)
Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between award recipients and the NIH may be brought to arbitration. An Arbitration Panel composed of three members will be convened. It will have three members: a designee of the Steering Committee chosen without NIH staff voting, one NIH designee, and a third designee with expertise in the relevant area who is chosen by the other two; in the case of individual disagreement, the first member may be chosen by the individual awardee. This special arbitration procedure in no way affects the awardee's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulations 42 CFR Part 50, Subpart D and HHS regulations 45 CFR Part 16.

3. Reporting

(This section must include general information about the type [e.g. financial or performance]

frequency, and means of submission [paper or electronic] of post award requirements. Highlight any special reporting requirements for awards under this funding opportunity that differ [e.g. by report type, frequency, form/format, or circumstances for use] from what the agency/ICs awards usually require.)
Add Information Here

Awardees will be required to submit the PHS Non-Competing Grant Progress Report, Form 2590 annually (http://grants.nih.gov/grants/funding/2590/2590.htm) and financial statements as required in the NIH Grants Policy Statement. (Add any IC specific reporting requirements not in the GPS or 2590.)

Section VII. Agency Contacts

We encourage your inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

1. Scientific/Research Contacts:

Use minimum information necessary in all addresses.
FAX Number is optional, Email address is required.

Staff Contact Name
Division
Institute or Center
Building Number, Room Number
Street Address
Bethesda, MD 20892
Telephone: (301) NNN-NNNN
FAX:
Email:

2. Peer Review Contacts:

(ordinarily only appropriate for PAR, if there will be no peer review contact, ICs should indicate N/A below in place of the contact information.)

Use minimum information necessary in all addresses.
FAX Number is optional, Email address is required.

Staff Contact Name
Division
Organization
Building Number, Room Number
Street Address
Bethesda, MD 20892
Telephone: (301) NNN-NNNN
FAX:
Email:

3. Financial or Grants Management Contacts:

Use minimum information necessary in all addresses.
FAX Number is optional, Email address is required.

Staff Contact Name
Division

Organization
Building Number, Room Number
Street Address
Bethesda, MD 20892
Telephone: (301) NNN-NNNN
FAX:
Email:

Section VIII. Other Information

Required Federal Citations

Choose all citations that are appropriate to the funding opportunity announcement.

Use of Animals in Research:
Recipients of PHS support for activated involving live, vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals (http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf) as mandated by the Health Research Extension Act of 1985 (http://grants.nih.gov/grants/olaw/references/hrea1985.htm), and the USDA Animal Welfare Regulations (http://www.nal.usda.gov/awic/legislat/usdaleg1.htm) as applicable.

Human Subjects Protection:
Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm).

Data and Safety Monitoring Plan:
Data and safety monitoring is required for all types of clinical trials, including physiologic toxicity and dose-finding studies (phase I); efficacy studies (Phase II); efficacy, effectiveness and comparative trials (Phase III). Monitoring should be commensurate with risk. The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

Sharing Research Data:
Investigators submitting an NIH application seeking $500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible (http://grants.nih.gov/grants/policy/data_sharing).

Investigators should seek guidance from their institutions, on issues related to institutional policies and local IRB rules, as well as local, State and Federal laws and regulations, including the Privacy Rule. Reviewers will consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

Sharing of Model Organisms:
NIH is committed to support efforts that encourage sharing of important research resources including the sharing of model organisms for biomedical research (see http://grants.nih.gov/grants/policy/model_organism/index.htm). At the same time the NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with Federal funding pursuant to the Bayh Dole Act (see the NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/index.htm). All investigators submitting an NIH application or contract proposal, beginning with the October 1, 2004 receipt date, are expected to include in the application/proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. This

will permit other researchers to benefit from the resources developed with public funding. The inclusion of a model organism sharing plan is not subject to a cost threshold in any year and is expected to be included in all applications where the development of model organisms is anticipated.

Inclusion of Women And Minorities in Clinical Research:
It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines is available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

Inclusion of Children as Participants in Clinical Research:
The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects (http://grants.nih.gov/grants/funding/children/children.htm).

Required Education on the Protection of Human Subject Participants:
NIH policy requires education on the protection of human subject participants for all investigators submitting NIH applications for research involving human subjects and individuals designated as key personnel. The policy is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

Human Embryonic Stem Cells (hESC):
Criteria for federal funding of research on hESCs can be found at http://stemcells.nih.gov/index.asp and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (http://escr.nih.gov). It is the responsibility of the applicant to provide in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s)to be used in the proposed research. Applications that do not provide this information will be returned without review.

Public Access to Research Data through the Freedom of Information Act:
The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm. Applicants may wish to place data collected under this funding opportunity in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

Standards for Privacy of Individually Identifiable Health Information:
The Department of Health and Human Services (DHHS) issued final modification to the "Standards for

Privacy of Individually Identifiable Health Information", the "Privacy Rule", on August 14, 2002 . The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (http://www.hhs.gov/ocr/) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

URLs in NIH Grant Applications or Appendices:
All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

Healthy People 2010:
The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople.

Authority and Regulations: (Be sure to cite any additional appropriate authorizations, regulations or policies below)
This program is described in the Catalog of Federal Domestic Assistance at http://www.cfda.gov/ and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at http://grants.nih.gov/grants/policy/policy.htm.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Loan Repayment Programs:
NIH encourages applications for educational loan repayment from qualified health professionals who have made a commitment to pursue a research career involving clinical, pediatric, contraception, infertility, and health disparities related areas. The LRP is an important component of NIH's efforts to recruit and retain the next generation of researchers by providing the means for developing a research career unfettered by the burden of student loan debt. Note that an NIH grant is not required for eligibility and concurrent career award and LRP applications are encouraged. The periods of career award and LRP award may overlap providing the LRP recipient with the required commitment of time and effort, as LRP awardees must commit at least 50% of their time (at least 20 hours per week based on a 40 hour week) for two years to the research. For further information, please see: http://www.lrp.nih.gov.

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